K121084

MAY - 9 2012

510(k) Summary of Safety and Effectiveness for the LOCI Cardiac Troponin-I Control (Low, Medium and High) (KC681, KC682, and KC683)

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

A. 510(k) Number:

B. Date of Preparation: April 5, 2012

C. Proprietary and Established Names:
LOCI Cardiac Troponin-I Control (low), LCTNI CON L (KC681)
LOCI Cardiac Troponin-I Control (medium), LCTNI CON M (KC682)
LOCI Cardiac Troponin-I Control (high), LCTNI CON H (KC683)

D. Applicant:
Siemens Healthcare Diagnostics Inc., P.O. Box 6101, Newark, DE 19714-6101
Frances A. Dillon, Sr. Manager. Regulatory Affairs
Tel: (302) 631-6951 Fax: (302) 631-6299

E. Regulatory Information:
1. Regulation Section: 21 CFR § 862.1660 Quality Control Material (Assayed and Unassayed)
2. Classification: Class I, reserve
3. Product Code: JJX – Single (Specified) Analyte Controls (Assayed and Unassayed)
4. Panel: Clinical Chemistry

F. Predicate Device:
The predicate device used to demonstrate substantial equivalence is the Abbott ARCHITECT *STAT* Troponin-I Controls, cleared under K041194.

G. Device Description:

LOCI Cardiac Troponin-I Control (low), LCTNI CON L
LCTNI CON L is a liquid, frozen, low level, human serum based product containing native human cardiac troponin complex. LCTNI CON L is packaged as 12 vials containing 2.2 mL quality control material per vial.

LOCI Cardiac Troponin-I Control (medium), LCTNI CON M
LCTNI CON M is a liquid, frozen, mid level, human serum based product containing native human cardiac troponin complex. LCTNI CON M is packaged as 12 vials containing 2.2 mL quality control material per vial.

LOCI Cardiac Troponin-I Control (high), LCTNI CON H
LCTNI CON H is a liquid, frozen, high level, human serum based product containing native human cardiac troponin complex. LCTNI CON H is packaged as 12 vials containing 2.2 mL quality control material per vial.

H. Intended Use:

LOCI Cardiac Troponin-I Control (low), LCTNI CON L
LCTNI CON L is an assayed, low level, intralaboratory quality control for assessment of precision and analytical bias in the quantitative determination of cardiac troponin-I (CTNI/TNI) on the Dimension Vista® System and Dimension® EXL™ integrated chemistry system with LOCI® module.

LOCI Cardiac Troponin-I Control (medium), LCTNI CON M
LCTNI CON M is an assayed, mid level, intralaboratory quality control for assessment of precision and analytical bias in the quantitative determination of cardiac troponin-I (CTNI/TNI) on the Dimension Vista® System and Dimension® EXL™ integrated chemistry system with LOCI® module.

LOCI Cardiac Troponin-I Control (high), LCTNI CON H
LCTNI CON L is an assayed, high level, intralaboratory quality control for assessment of precision and analytical bias in the quantitative determination of cardiac troponin-I (CTNI/TNI) on the Dimension Vista® System and Dimension® EXL™ integrated chemistry system with LOCI® module.

I. Substantial Equivalence Information:

The LOCI Cardiac Troponin-I Control (Low, Medium and High) was compared to the predicate device, Abbott ARCHITECT *STAT* Troponin-I Controls, cleared under K041194. The following tables provide a comparison of the important similarities and differences between the devices:

Similarities and Differences

Feature	New Device LOCI Cardiac Troponin-I Control L, M and H	Predicate ARCHITECT *STAT* Troponin-I Controls, K041194
Intended Use	LCTNI CON L, M and H are assayed, intralaboratory quality controls for assessment of precision and analytical bias in the quantitative determination of cardiac troponin-I (CTNI/TNI)) on the Dimension Vista® System and Dimension® EXL™ integrated chemistry system with LOCI® module.	The ARCHITECT *STAT* Troponin-I Controls are for verification of the accuracy and precision of the ARCHITECT *i* System with *STAT* protocol capability when used for the quantitative determination of cardiac troponin-I (cTnI) in human serum and plasma.
Product Code	JJX	JJX
Assayed Control	Yes	Yes
Constituents	Native human cardiac troponin complex	Recombinant human cardiac troponin IC complex
Matrix	Human serum	BES buffer
Form	Liquid, frozen	Liquid, frozen
Levels Available	Three – L, M and H	Three – L, M and H
Package Configuration	12 vials x 2.2 mL per vial. One level per carton	6 vials x 3.0 mL each level; 2 x 3 x 3.0 mL, 2 vials of each level.

J. Performance:

The traceability, value assignment, stability and matrix effects of the LOCI Cardiac Troponin-I Control L, M and H have been validated following procedures of Siemens Healthcare Diagnostics, Inc.

K. Conclusion:

LOCI Cardiac Troponin-I Control (low), LOCI Cardiac Troponin-I Control (medium) and LOCI Cardiac Troponin-I Control (high) are substantially equivalent in design and intended use to the previously cleared Abbott ARCHITECT *STAT* Troponin-I Controls (K041194).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

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Silver Spring, MD 20993

Siemens Healthcare Diagnostics, Inc
c/o Frances A. Dillon
P.O. Box 6101
Mailstop 514
Newark, Delaware 19714-6101

JUN - 1 2012

Re: k121084
Trade Name: LOCI Cardiac Troponin-I Control (Low), LCTN1 Con L
LOCI Cardiac Troponin-I Control (Medium), LCTNI CON M
LOCI Cardiac Troponin-I Control (High), LCTNI CON H
Regulation Number: 21 CFR §862.1660
Regulation Name: Quality control material (assayed and unassayed)
Regulatory Class: Class I, Reserved
Product Codes: JJX
Dated: April 6, 2012
Received: April 10, 2012

Dear Ms. Dillon:

This letter corrects our substantially equivalent letter of May 9, 2012.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance...

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm

Sincerely yours,

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: LOCI Cardiac Troponin-I Control (low), LCTNI CON L
LOCI Cardiac Troponin-I Control (medium), LCTNI CON M
LOCI Cardiac Troponin-I Control (high), LCTNI CON H

Indications for Use:

LOCI Cardiac Troponin-I Control (low), LCTNI CON L
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LOCI Cardiac Troponin-I Control (high), LCTNI CON H
LCTNI CON H is an assayed, high level, intralaboratory quality control for assessment of precision and analytical bias in the quantitative determination of cardiac troponin-I (CTNI/TNI) on the Dimension Vista® System and Dimension® EXL™ integrated chemistry system with LOCI® module.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K121084